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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,630	01/02/2001	Syed F.A. Hossainy	M-8618 US	1934

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EXAMINER
MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
1762	7

DATE MAILED: 03/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/753,630	HOSSAINY ET AL.	
	Examiner	Art Unit	
	Jennifer Kolb Michener	1762	

-- The MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-14,19-21 and 26-59* is/are pending in the application.

4a) Of the above claim(s) *12-14,19-21 and 26-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

As necessitated by Applicant's amendment, the following new 112 rejections are made:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 38, 44, and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is confusing. Examiner wishes to be certain that the therapeutic substance of claim 38 is not the same as the heparin therapeutic substance required by claim 37.

Claim 44 is confusing. Does the phrase "said coating" refer to the coating of claim 37 or the primer coating of claim 43?

The recitation of the brand-name "DURAFLO" in claim 48 renders the claim indefinite because it does not indicate whether the same material made under a different name is equally operational. Moreover, the value of the trademark name is lost to the extent that it becomes descriptive of a product rather than the identification of a source or an origin of a product.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The rejection of claims 1-2, 4, 15-17 under 35 U.S.C. 102(e) as being anticipated by Zhong has been withdrawn, as necessitated by Applicant's cancellation of the claims.

5. The rejection of claims 1, 2, 4, and 5 under 35 U.S.C. 102(b) as being anticipated by Tuch has been withdrawn as necessitated by Applicant's cancellation of the claims.

As necessitated by Applicant's amendment, the following new 102 rejections are made:

6. Claims 37 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowland et al. (5,356,433)

Rowland teaches coating stents with an ionic complex of heparin and TDMAC (comparative example). As taught in Applicant's instant disclosure, heparin complexes with TDMAC are examples of a "heparin compound having a hydrophobic counter ion" as required by the claim.

7. Claims 37 and 49-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Shah et al. (US 6,248,127 B1).

Shah et al. teach coating a stent (col. 6, line 6) with a heparin-TDMAC complex , chloro-silane, and other additives which improve adherence to the substrate (col. 5, line 39, col. 4, lines 13 and 48). To aid in forming a film, polyurethanes, caprolactone, or the like may be used (col. 6, lines 20-25), which would act as adhesion promoters required by Applicant.

Shah dips the stents of his invention (col. 7, line 53)

8. Claims 37, 41, 48-51 and 58-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Ding et al. (US 6,316,018 B1).

Ding et al. teaches coating stents (col. 4, line 65) with a reservoir layer of a polymer (abstract), which acts as a primer or adhesion enhancer, followed by a surfactant-drug complex (col. 8, line 40). The surfactant of Ding may be TDMAC and the drug of Ding may be heparin (col. 8). Following coating, the stents are heat-treated in an oven at 90 °C (example 1). The reservoir layer polymer of Ding may be polyurethane, among other examples (col. 5).

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. The rejection of claims 3, 18, and 22 under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Hostettler et al. '960 has been withdrawn as necessitated by Applicant's cancellation of the claims.

11. The rejection of claims 15-18 and 22-24 under 35 U.S.C. 103(a) as being unpatentable over Fox, Jr. et al. has been withdrawn as necessitated by Applicant's cancellation of the claims.

12. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over Hostettler '656 has been withdrawn as necessitated by Applicant's cancellation of the claims.

13. The rejection of claims 6-11 under 35 U.S.C. 103(a) as being unpatentable over Hostettler '656 in view of Nygren et al has been withdrawn as necessitated by Applicant's cancellation of the claims.

As necessitated by Applicant's amendment, the following new rejections are made:

14. Claims 37-38, 41, 44, 48-51, 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Shah et al.

Zhong teaches coating an implantable medical device, such as a stent, with a bio-compatible coating containing polyurethane. Such a coating can serve as a topcoat or serve as a primer for a second coating layer that contains certain bio-active agents (abstract, col. 1, lines 14 and 30). After application of the coating, it is dried, to attach the coating to the substrate. The stent substrate may be metal. (col. 3, line 60 and col. 8, lines 18 and 32). When used as a primer, the coating contains organic acid functional groups, such as carboxyl groups, reactive with subsequently applied thrombo-resistant agents (paragraph bridging cols 3 and 4 and col. 4, line 52). Zhong teaches that all layers may be applied by dipping (col. 6, lines 34 and 67). The bio-active agent of the second coating may be a thrombo-resistant agent, such as heparin

or its homologs, analogs, fragment, and derivatives thereof (col. 7, lines 14-28). Further, Zhong teaches that multiple layers of the polyurethane-containing coating may be used alone or in combination with multiple layers of the bio-active agent coatings.

What Zhong fails to specifically teach is the use of heparin with "a hydrophobic counter ion". It is the Examiner's position that Zhong's broad class of heparin and its derivatives would be inclusive of heparin complexed with TDMAC, a hydrophobic counter ion. Examiner notes that the heparin-TDMAC complex is well-known in the art of coating medical devices, such as metallic stents and cites Shah to teach the same. Shah teaches coating metallic stents with heparin and teaches that the use "of the term 'heparin' herein should be understood to include heparin, as well as any other heparin complex, including heparin-tri(dodecyl)methylammonium chloride complex." (col. 2, line 65).

It would have been obvious to one of ordinary skill in the art to select a heparin-TDMAC complex from the broad class of "heparin and its derivatives" with the expectation of similar, successful results as stent coatings.

In regard to the temperature range of the heat treatment, it would have been obvious to one having ordinary skill in the art to have determined the optimum values of the relevant process parameters through routine experimentation in the absence of a showing of criticality. *In re Aller*, USPQ 233 (CCPA 1955).

15. Claims 40, 43, 52-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong in view of Shah as applied to claims 37-38, 41, 44, 49-51, 58-59 above, and further in view of Hostettler '960.

Zhong and Shah teach that which is disclosed above, but fail to teach roughening the surface of the substrate prior to coating.

Hostettler teaches roughening of a medical substrate prior to applying polyurethane-based coatings (col. 13, line 47). Since Zhong and Hostettler teach application of polyurethane-based coatings to medical devices and Hostettler teaches pre-treatment by roughening the substrate, Hostettler would have reasonably suggested roughening the surface of Zhong's device prior to coating. It would have been obvious to one of ordinary skill in the art to use the teachings of Hostettler in the method of Zhong and Shah to roughen the surface of Zhong's substrate prior to coating to increase the surface area of the substrate and thus enhance adhesion of the coating.

Hostettler teaches argon plasma pre-treatment which will inherently act as the roughening argon plasma pre-treatment step required by Applicant (col. 16, line 16).

16. Claims 37-38, 40-43, 45-53, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hostettler '656 in view of Shah.

Hostettler '656 teaches a method of coating stents with tenaciously adhering coatings of polyurethane (abstract). Prior to coating with the polyurethane-based coating, Hostettler teaches application of an aminosilane primer to the surface (col. 14, lines 27-34), such as trimethoxysilane. Hostettler teaches the use of the broad class of

"polysaccharides" as coatings on amine-treated medical devices. The patent discloses the use polysaccharides, such as heparin, as a coating for amine-treated medical devices in the prior art (col. 4, line 52). Since heparin is a polysaccharide commonly used in medical device coatings as it provides thromboresistant properties, Hostettler's teaching of polysaccharides as a broad class would be inclusive of heparin and its derivatives and it would have been obvious to one of ordinary skill to select heparin as a suitable and useful polysaccharide in the method of Hostettler. Shah is cited for those reasons outlined above regarding the selection of TDMAC-heparin from the broad class of heparin derivatives.

Hostettler teaches roughening of the substrate prior to application of the primer (col. 10, line 28).

While Hostettler teaches the use of aminosilanes for use in adhering the heparin coating to the stent substrate, he fails to specifically teach the use of chlorosilanes. Shah teaches a number of silanes useful in linking heparin to stent substrates, such as trialkoxysilanes and chlorosilanes (col. 5, lines 34-42). Since Hostettler teaches the use of trimethoxysilanes as a coupling agent and Shah teaches the use of trialkoxysilanes (of which trimethoxysilane is a member) and chlorosilanes, Shah would have reasonably suggested the use of chlorosilanes as a coupling agent in Hostettler. It would have been obvious to one of ordinary skill in the art to interchange the chlorosilane of Shah for the trimethoxysilane of Hostettler with the expectation of similar successful results in adhering heparin to metallic stents.

17. Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onishi in view of Shah.

Onishi teaches coating stents with heparin in an ethylene vinyl alcohol copolymer (col. 8, line 45; col. 11, lines 40-60; col. 12, line 60). While Onishi et al. fail to specifically teach the use of heparin with "a hydrophobic counter ion", Shah is cited for teaching that the heparin-TDMAC complex is a commonly used heparin derivative. It would have been obvious to one of ordinary skill in the art to use the teachings of Shah in the method of Onishi in selecting heparin-TDMAC from the broad class of heparin disclosed by Onishi.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3599 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer Kolb Michener
March 6, 2002

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